

Claim 16, another independent claim which is directed to a method of inhibiting growth or recurrent growth of a melanoma tumor in a mammal having melanoma or at risk for melanoma growth or recurrence, was not said to be a linking claim; claims 17-21 depend therefrom. Claims 16 and various of its dependent claims are included in each of Groups I-X.

The allegedly distinct Groups, as defined by the Office, are summarized below:¹

- Group I.** Claims 1-3, 6-7, 9-12, 15-18, 21 -- method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using one inhibitor of the MAPK pathway, *Bacillus anthracis* lethal factor (a MEK1 and MEK2-directed protease).
- Group II.** Claims 1-2, 6-7, 9-11, 15-17, 21 -- a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using one inhibitor of the MAPK pathway, a *Yersinia* protein (which is a MEK1-directed protease disclosed in the specification on page 12).
- Group III.** Claims 1, 4-7, 9-10, 13-16, 19-21 -- a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using one small organic molecule inhibitor of the MAPK pathway, PD98059.
- Group IV.** Claims 1, 4-7, 9-10, 13-16, 19-21 -- a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using one small organic molecule inhibitor of the MAPK pathway, U0126.
- Group V.** Claims 1, 4-7, 9-10, 13-16, 19-21 -- a method of killing melanoma cells or inducing an antitumor response in a mammal having melanoma, using one small organic molecule inhibitor of the MAPK pathway, PD184352.
- Group VI.** Claims 8, 16-18, 21 -- a method for *protecting against* melanoma in a susceptible subject by administering one inhibitor of the MAPK pathway -- *Bacillus anthracis* lethal factor.
- Group VII.** Claims 8, 16-18, 21 -- a method for *protecting against* melanoma in a susceptible subject, by administering one inhibitor of the MAPK pathway, a *Yersinia* protein.
- Group VIII.** Claims 8, 16, 19-21 -- a method for *protecting against* melanoma in a susceptible subject, by administering one small organic molecule inhibitor of the MAPK pathway, PD98059.
- Group IX.** Claims 8, 16, 19-21 -- a method for *protecting against* melanoma in a susceptible subject, by administering one small organic molecule inhibitor of the MAPK pathway, U0126.
- Group X.** Claims 8, 16, 19-21 -- a method for *protecting against* melanoma in a susceptible subject, by administering one small organic molecule inhibitor of the MAPK pathway, PD184352.

¹ paraphrased from the Office Action

RESPONSE

The undersigned discussed this Restriction Requirement with the Examiner in a phone conference, but is still somewhat confused as to why, for example the claims that recite 3 small organic molecule inhibitors are not considered a species or subgenus of a generic (or a "higher" subgeneric) claim, *e.g.*, claims 4, 13 or 19, that reads on a small organic molecule MAPK pathway inhibitor. It would be appropriate to elect one of these compounds as a species for initial examination, and if found patentable over the art, to examine the generic (or subgeneric) claims (claim 4, 13 or 19) for their full scope.

Applicants traverse the requirement that improperly treats the three small organic molecule inhibitors as distinct inventions rather than species of which one must be elected, particularly in view of the fact that there is appear claims that are generic to these species. The same would hold true for the proteinaceous MAPK pathway inhibitors which are claimed as the genus (or subgenus) "MEK-directed proteases" (*e.g.*, claims 2, 11 or 17). *B. anthracis* lethal factor is but one species of this genus (*e.g.*, claims 3, 12 or 18). It would have been appropriate to require an election of species (*e.g.*, *B. anthracis* lethal factor vs. the Yersinia protein disclosed, but not claimed specifically) for initial examination.

Ultimately, the protein-based MAPK pathway inhibitors and small organic molecule MAPK pathway inhibitors are species (or subgenera) of the generic claims to "MAPK pathway inhibitors" as claimed in claims 1, 8, 9 and 16.

For initial examination, Applicants elect, with traverse, Group V, which focuses on the species PD184352, one small organic molecule inhibitor of the MAPK pathway. Claims 1, 4-7, 9-10, 13-16, 19-21 are to be examined to the extent that they read on this molecule.

Applicants request that this be treated as an election of species as well, such that, when these claims are found to be free of any prior art with respect to PD184352, the examination will initially be extended to the other two small organic molecule inhibitors constituting the genus of small organic molecule MAPK pathway inhibitors in all 14 of the foregoing elected claims.

Finally, once linking claim 1 (and properly, generic claims 9 and 16) are found to be patentable over the prior art with respect to the compound PD184352 and the other two recited small organic compounds, the scope of examination in this case, without need for a divisional, will be enlarged to include the full genus of MAPK pathway inhibitors of the linking claims. Under this

election and Applicants' analysis as set forth herein, the only claims that need to be withdrawn and which will require a divisional application for their examination are:

- (a) claims directed to the "subgenus" of MEK-directed protease inhibitors of the MAPK pathway, such as the *B. anthracis* lethal factor (claims 2, 3, 11, 12, 17, 18); and
- (b) the claim directed to a method of protecting against melanoma in a susceptible subject (claim 8).

Thus, Applicants hereby withdraw claims 2, 3, 8, 11, 12, 17 and 18, from consideration as being directed to nonelected inventions.

Applicants believe that the claims are now in condition for examination on the merits. If Applicants' representative has misunderstood the Examiner's intent, the Examiner is respectfully requested to contact the undersigned at 202.216.8584 to clarify the Restriction Requirement and verify that Applicants election indeed places the case in condition for examination.

While it is believed that no additional fees are required, in the unlikely event that the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due to Deposit Account 22-0261. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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